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INNOVATION OR INFLUENCE: INDUSTRY'S EFFECT ON SURGERY

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About Notable Grand Rounds

These assembled papers are edited transcripts of didactic lectures given by mainly senior residents, but also some distinguished attending and guests, at the Grand Rounds of the Michael and Marian Ilitch Department of Surgery at the Wayne State University School of Medicine.

Every week, approximately 50 faculty attending surgeons and surgical residents meet to conduct postmortems on cases that did not go well. That "Mortality and Morbidity" conference is followed immediately by Grand Rounds.

This collection is not intended as a scholarly journal, but in a significant way it is a peer reviewed publication by virtue of the fact that every presentation is examined in great detail by those 50 or so surgeons.

It serves to honor the presenters for their effort, to potentially serve as first draft for an article for submission to a medical journal, to let residents and potential residents see the high standard achieved by their peers and expected of them, and by no means least, to contribute to better patient care.

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Innovation or Influence: Industry's Effect on Surgery

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Introduction and Historical Foundations

The relationship between surgery and industry is neither incidental nor recent; it is foundational. From its earliest developments, surgical progress has depended not only on the ingenuity of individual physicians but also on the capacity to translate ideas into reproducible, scalable tools. That translation—moving from concept to widespread clinical adoption—has consistently required collaboration with industry. Yet embedded within this relationship is a persistent tension: the same mechanisms that enable innovation also introduce the potential for influence, bias, and conflict.

Modern surgery is often defined by its technologies—robotic platforms, endovascular devices, advanced imaging systems, and implantable biomaterials. These are not merely adjuncts to surgical practice; they are constitutive of it. It is difficult to conceive of contemporary operative care without industry participation, whether in the development of minimally invasive instrumentation, vascular devices, or energy platforms. This interdependence raises a central question: how can the profession preserve the benefits of innovation while maintaining the integrity of clinical judgment?

To address this question, it is necessary to understand how the surgeon–industry relationship evolved. Historically, surgical innovation was largely physician-driven, particularly prior to the 19th century, when individual practitioners developed techniques and tools in relative isolation. However, the 19th century marked a decisive shift toward collaboration. The introduction of ether anesthesia[2] at Massachusetts General Hospital in 1846, later commercialized, demonstrated the transformative potential of scalable medical technologies. Similarly, Joseph Lister's application of phenol for antisepsis in 1867 and the subsequent industrial production of sterile dressings by Johnson & Johnson[3] reflected an emerging partnership between scientific discovery and manufacturing capability.

This collaboration deepened toward the end of the century. The introduction of surgical gloves[4] by William Halsted, facilitated through partnership with the Goodyear company, exemplified how industrial expertise could rapidly disseminate innovations that improved both surgeon safety and patient outcomes. By the early 20th century, this model had become firmly established. The development of the electrosurgical unit by William Bovie and its clinical application by Harvey Cushing in 1926[5] represented a convergence of engineering and surgical practice that would fundamentally alter operative technique. Likewise, John Gibbon's heart–lung machine,[6] developed in collaboration with IBM and first used clinically in 1953, extended the boundaries of what surgery could accomplish by enabling cardiopulmonary bypass.

The latter half of the 20th century saw an acceleration of this trend. Surgical stapling devices, initially developed in the Soviet Union, were introduced and scaled in the United States through commercial manufacturing, transforming gastrointestinal and thoracic surgery by improving efficiency and consistency. The advent of laparoscopy further underscored the centrality of industry, as companies such as Karl Storz and Ethicon produced the optics, insufflation systems, and instrumentation necessary for minimally invasive techniques to proliferate.

By the 21st century, the integration of surgery and industry had become comprehensive. Robotic platforms such as those developed by Intuitive Surgical, along with advances in endovascular therapy, image-guided surgery, stereotactic techniques, extracorporeal support systems, and personalized medicine, illustrate a landscape in which technological innovation is inseparable from industrial capability. At the same time, this era has been characterized by the emergence of "key opinion leaders,"the normalization of industry-sponsored education and travel, and a series of high-profile device-related controversies, including the metal-on-metal hip implant crisis and the power morcellator debate.

These developments collectively demonstrate that the relationship between surgery and industry is not a modern complication imposed upon an otherwise independent profession. Rather, it is an intrinsic feature of surgical progress. The challenge, therefore, is not whether this relationship should exist, but how it should be structured, governed, and critically examined.

The sections that follow explore this relationship in greater detail, examining its economic scale, its contributions to clinical advancement, the nature of conflicts of interest that arise, and the regulatory frameworks designed to manage them. Ultimately, the goal is to define a path forward that preserves innovation while maintaining the primacy of patient-centered care.

Modern Industry Landscape and Economic Structure

The contemporary relationship between surgery and industry must be understood within the context of a vast and highly structured economic ecosystem. What was once a series of ad hoc collaborations between individual surgeons and craftsmen has evolved into a global enterprise characterized by multinational corporations, complex supply chains, and substantial financial influence. The scale of this system is not merely descriptive; it shapes the conditions under which surgical innovation occurs and the incentives that guide it.

The medical device sector alone represents a major component of the healthcare economy. The current market capitalization of the medical device industry is approximately $779.5 billion, accounting for roughly 11% of the healthcare sector, with over 578,000 employees across 158 companies.[7] Forecasts suggest continued expansion, with a projected compound annual growth rate of 6.9% and an anticipated valuation exceeding $1 trillion by 2034. This growth reflects not only increasing demand for technologically advanced care but also the ongoing integration of devices into nearly every domain of surgical practice.

In contrast, the pharmaceutical industry operates at an even larger scale, with an estimated market capitalization of $3.1 trillion and representing approximately 42.7% of the healthcare sector.[8] Despite this disparity in size, the nature of physician interaction differs meaningfully between the two sectors. The relationship between surgeons and device manufacturers is often more direct and symbiotic than that between physicians and pharmaceutical companies. Surgical devices are not simply prescribed; they are selected, manipulated, and, in many cases, iteratively refined through feedback from the operating room. This creates a dynamic in which surgeons are not only end-users but also contributors to product development.

This structural distinction has important implications. Device innovation frequently depends on close collaboration between clinicians and engineers, often involving iterative prototyping, intraoperative evaluation, and rapid modification cycles. Unlike pharmaceuticals, which undergo relatively centralized development and testing, devices may evolve in a more distributed and practice-driven manner. While this can accelerate innovation, it also introduces variability and potential vulnerabilities in evaluation and oversight.

The breadth of industry's contribution to surgical practice is extensive and can be appreciated by examining specific domains. Minimally invasive surgery, for example, depends entirely on industry-produced components: optical systems, light sources, trocars, insufflators, cameras, and specialized instruments. These technologies, developed and refined by companies such as Olympus Corporation, Boston Scientific, and Medtronic, have enabled procedures that reduce morbidity, shorten hospital stays, and expand the range of treatable conditions.

Similarly, robotic surgery platforms, most prominently those produced by Intuitive Surgical, have introduced new paradigms of precision and ergonomics, while also reshaping training, credentialing, and institutional investment strategies. Vascular surgery provides another clear example: catheters, stents, and endografts—manufactured by companies such as W. L. Gore & Associates and Terumo—have facilitated the transition from open to endovascular approaches, fundamentally altering patient care pathways.

The same pattern extends across subspecialties. Orthopedic surgery relies on implants, fixation devices, and instrumentation produced by firms such as Stryker Corporation and Zimmer Biomet. Energy devices, including electrosurgical units and advanced vessel-sealing systems, are integral to daily operative practice. Even adjunctive technologies—such as indocyanine green (ICG) imaging, intravascular ultrasound (IVUS), and neuromonitoring—are products of sustained industrial development.

Beyond tangible products, industry exerts influence through less visible but equally significant channels. Clinical trials, particularly large multicenter studies, often depend on industry funding due to the substantial costs involved.[9] Trials such as PARTNER (transcatheter aortic valve replacement), EXCEL (PCI vs CABG), and EVAR studies exemplify the central role of industry in generating evidence that shapes clinical practice. In many cases, the scale and logistical complexity of these trials would exceed the capacity of traditional public funding mechanisms.

Industry also contributes to the infrastructure of surgical education. Fellowship programs, simulation platforms, and proctoring systems frequently rely on industry support, particularly in emerging fields where procedural volumes may initially be low. Even foundational training tools for skills certification—such as those used in Fundamentals of Laparoscopic Surgery (FLS)—are products of industry collaboration. While this support facilitates dissemination and standardization of new techniques, it also introduces dependencies that must be carefully managed.

Taken together, these factors illustrate that industry is not peripheral to modern surgery; it is deeply embedded within its economic, technological, and educational structures. The relationship is productive, often indispensable, and in many respects mutually reinforcing. However, this same integration creates conditions in which financial, professional, and institutional incentives may intersect with clinical decision-making.

We now examine these intersections more closely, focusing on the concept of conflict of interest and the mechanisms through which influence may be exerted within the surgeon–industry relationship.

Benefits and Clinical Impact of Industry Collaboration

Any critical appraisal of the relationship between surgery and industry must begin with a clear acknowledgment: modern surgical practice, in its current form, would not exist without industry participation. This is not a rhetorical claim but a practical reality. The tools, platforms, and systems that define contemporary operative care—particularly those associated with minimally invasive and image-guided techniques—are products of sustained industrial development, refinement, and distribution.

At the most immediate level, industry enables the creation and scaling of surgical technologies. Minimally invasive surgery provides a representative example. The transition from open to laparoscopic approaches required not only conceptual innovation but also the coordinated development of optics, light sources, insufflation systems, trocars, and specialized instruments. These components, produced by manufacturers with the capacity for precision engineering and large-scale distribution, transformed what might otherwise have remained isolated innovations into globally adopted standards of care. The same can be said of robotic platforms, which have introduced enhanced dexterity, visualization, and ergonomics, enabling procedures that were previously impractical or technically prohibitive.

This pattern extends across surgical subspecialties. In vascular surgery, the development of catheters, stents, and endografts has facilitated the shift toward endovascular interventions, reducing operative morbidity and expanding treatment options for high-risk patients. In cardiothoracic surgery, extracorporeal circuits and cannulation systems have made complex procedures such as cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO) feasible and reproducible. Orthopedic surgery is similarly dependent on implants, fixation systems, and instrumentation that allow for joint replacement, spinal stabilization, and trauma reconstruction. Energy devices, including advanced vessel-sealing technologies and ultrasonic scalpels, have improved intraoperative efficiency and hemostasis, becoming routine components of daily surgical practice.

Importantly, the contribution of industry extends beyond the production of devices to the generation of clinical evidence. Large-scale, multicenter trials—often essential for establishing the safety and efficacy of new technologies—frequently rely on industry sponsorship due to their substantial financial and logistical requirements. Trials such as PARTNER (evaluating transcatheter aortic valve replacement), EXCEL (comparing percutaneous coronary intervention with coronary artery bypass grafting), and EVAR studies in vascular surgery exemplify this dynamic. In many cases, these investigations have directly informed clinical guidelines and practice patterns, accelerating the adoption of new therapeutic approaches.

In addition to premarket evaluation, industry plays a significant role in post-market surveillance and registry development. Longitudinal data collection through registries—such as those established in orthopedic surgery to monitor implant performance—has facilitated the identification of device-related complications and informed iterative improvements. These systems provide a mechanism for real-world evaluation that complements controlled clinical trials, offering insights into long-term outcomes and rare adverse events.

Another critical domain of industry involvement is surgical education and training. Fellowship programs, particularly in technically demanding or rapidly evolving fields, often depend on industry support during their formative stages. Some programs have historically required such support due to limited procedural volume, particularly when introducing new technologies. Industry-sponsored proctoring programs further facilitate the dissemination of novel techniques by enabling experienced surgeons to train others in a structured and scalable manner. This is particularly evident in the adoption of robotic platforms, where standardized training pathways have been essential to safe implementation.

Simulation-based education represents another area in which industry contributions have been substantial. Training models and certification systems, including those used for laparoscopic and endoscopic skill acquisition, rely on commercially developed platforms that allow for repetitive practice in a controlled environment. These tools have contributed to the standardization of surgical education, improving both competency assessment and patient safety.

Despite these substantial benefits, it is essential to recognize that the mechanisms enabling innovation and dissemination are the same mechanisms through which influence may be exerted. The capacity to fund trials, support training programs, and shape the development of new technologies inherently confers a degree of power within the clinical ecosystem. The central problem is not the existence of industry or even its pursuit of profit; rather, it is the difficulty of capturing the benefits of this relationship without simultaneously introducing conflicts of interest.

This duality—innovation coupled with influence—forms the basis for the following examination of the concept of conflict of interest in greater detail, including its definitions, manifestations, and implications for surgical practice.

Conflicts of Interest: Definitions, Types, and Conceptual Framework

The benefits of industry collaboration are substantial and, in many respects, indispensable. However, the same structures that enable innovation also create conditions in which professional judgment may be influenced—subtly or overtly—by competing interests. The concept of conflict of interest (COI) is therefore central to any rigorous analysis of the surgeon–industry relationship.

A conflict of interest is best understood not as evidence of wrongdoing, but as a set of circumstances that creates a risk that professional decisions regarding a primary interest may be influenced by a secondary interest. In the surgical context, the primary interest is typically the welfare of the patient or the integrity of a research objective. Secondary interests, by contrast, include financial gain, career advancement, professional recognition, or institutional priorities.

This distinction is critical. A conflict of interest is not a character flaw. Rather, it is analogous to situations in other professional domains—for example, a judge recusing herself or himself from a case involving a family member. The presence of a conflict does not imply bias or misconduct; it indicates the potential for influence. This conceptual clarity is essential, as it shifts the discussion from moral judgment to structural analysis.

Conflicts of interest in surgery can be broadly categorized into three domains: financial, reputational, and institutional.

Financial conflicts are the most visible and frequently discussed. These include consulting fees, royalties from device development, equity or stock ownership in companies, speaker honoraria, research funding, and industry-sponsored travel or meals. Such relationships may arise naturally in the course of collaboration, particularly when surgeons contribute to the design or evaluation of new technologies. However, they also create a direct linkage between financial benefit and clinical decision-making, which may influence device selection, procedural recommendations, or interpretation of outcomes.

Reputational conflicts are less tangible but equally significant. Surgeons who pioneer new techniques or technologies often have a professional stake in their success. An individual who develops a novel procedure may be predisposed—consciously or unconsciously—to view its outcomes favorably, particularly when their professional identity is closely associated with that innovation. This form of conflict is inherent to academic and clinical advancement, where recognition and reputation are key drivers of career progression.

Institutional conflicts arise at the level of healthcare systems and organizations. Hospitals that invest heavily in specific technologies—such as robotic surgical platforms—may shape clinical practice patterns to justify those investments. This can influence credentialing processes, operating room scheduling, purchasing decisions, and even the development of service lines. In such cases, the institution itself becomes a stakeholder, with financial and strategic interests that may intersect with patient care decisions.

It is important to emphasize several principles that emerge from this framework. First, the presence of a conflict of interest does not constitute proof of bias or wrongdoing. Many surgeons maintain professional integrity despite complex relationships with industry. Second, conflicts are not unique to surgery; they are present across medical specialties and, indeed, across professions.

Third, and perhaps most importantly, conflicts of interest are not resolved by disclosure alone. While transparency is necessary, it is insufficient as a sole mechanism of mitigation. Disclosure shifts the burden of interpretation to the patient or audience, who may lack the context or expertise to assess the significance of the disclosed relationship. Moreover, there is evidence that disclosure can paradoxically increase bias, either by creating a sense of moral license in the disclosing party or by normalizing the presence of such relationships.

This raises a practical and ethically salient question: if a patient were fully aware of a surgeon's financial or professional relationship with a device manufacturer, would that knowledge alter their perception of the recommendation being made? The answer to this question is not uniform, but its very existence underscores the importance of addressing conflicts of interest as structural features of the system rather than as isolated ethical lapses.

Transparency and Regulation: Sunshine Act, Open Payments, and ACCME

Recognition of the structural nature of conflicts of interest has led, over the past several decades, to the development of formal mechanisms intended to increase transparency and mitigate undue influence. These efforts reflect an evolving consensus: while the relationship between surgeons and industry cannot—and should not—be eliminated, it must be rendered visible, accountable, and subject to oversight.

The most prominent legislative response in the United States is the Physician Payments Sunshine Act, enacted in 2010 as part of the Affordable Care Act. The central aim of this legislation is to increase transparency in financial relationships between physicians and industry. Specifically, it mandates that manufacturers of drugs, medical devices, and biologics report payments and transfers of value made to physicians and teaching hospitals to the Centers for Medicare & Medicaid Services (CMS).

These reported transactions encompass a wide range of interactions, including consulting fees, speaking engagements, research funding, gifts, entertainment, travel, food and beverage, and support for medical education. Notably, the reporting threshold is relatively low—generally $10—reflecting an intent to capture even modest financial exchanges. The resulting data are made publicly accessible through the Open Payments database, allowing patients, institutions, and researchers to examine the financial relationships of individual physicians.

The scale of these interactions is substantial. An analysis published in JAMA reported that between 2013 and 2022, approximately 85 million instances of payments were made to 820,000 physicians, totaling roughly $12 billion. The distribution of these payments is not uniform; specialties such as orthopedic surgery, cardiology, and neurology/psychiatry receive a disproportionate share, reflecting their close association with device- and technology-driven care. Importantly, these data are not abstract—they are searchable at the individual physician level, making financial relationships a matter of public record.[10]

While transparency is a necessary first step, it does not, in itself, resolve the challenges posed by conflicts of interest. As previously noted, disclosure alone may be insufficient and can even have unintended consequences. Accordingly, additional layers of oversight have been developed within the domain of continuing medical education (CME).

The Accreditation Council for Continuing Medical Education (ACCME) plays a central role in this regard. As a nonprofit accrediting body, ACCME establishes standards for the identification, mitigation, and disclosure of financial relationships in educational activities. Institutions offering CME are required to collect detailed information regarding all financial relationships between faculty and "ineligible companies" (i.e., those whose primary business is producing, marketing, selling, or distributing healthcare products used by patients) within the preceding 24 months.

These relationships must then be evaluated to determine whether they are relevant to the content of the educational activity. Where relevance is identified, institutions are required to implement mitigation strategies, which may include peer review of content, modification of presentations, or exclusion of conflicted individuals from certain roles. Finally, these relationships must be disclosed to learners, typically at the beginning of a lecture or educational session.

The ACCME framework also delineates specific exceptions. Non-clinical educational activities—such as those focused on leadership or communication skills—may not require disclosure. Similarly, educational formats in which learners control the content, such as spontaneous case discussions or self-directed learning activities, are treated differently, reflecting a lower risk of commercial influence.

Despite these efforts, important limitations remain. Transparency mechanisms rely on the assumption that stakeholders—patients, learners, and institutions—are able to interpret disclosed information effectively. In practice, this assumption is not always valid. The significance of a given financial relationship may be difficult to assess without contextual knowledge, and the presence of disclosure may inadvertently normalize or legitimize the relationship.

Moreover, transparency does not address more diffuse forms of influence, such as reputational or institutional conflicts, which may not be easily quantified or reported. Nor does it fully mitigate the structural incentives embedded within the system, particularly in areas where industry funding is essential to the conduct of research or the dissemination of new technologies.

These considerations highlight a recurring theme: regulatory frameworks can illuminate and, to some extent, constrain the surgeon–industry relationship, but they cannot eliminate the underlying tensions. As such, understanding the mechanisms by which devices are evaluated and approved becomes critical.

Medical Device Classification and Regulatory Pathways

The regulation of medical devices represents a central point at which innovation, industry influence, and patient safety intersect. Unlike pharmaceuticals, which follow a relatively uniform pathway for development and approval, medical devices are governed by a tiered regulatory framework that reflects varying levels of risk. Understanding this framework is essential to appreciating both the strengths and vulnerabilities of the current system.

In the United States, medical devices are classified into three categories based on the degree of risk they pose to patients. **Class I** devices are considered low risk and include items such as oxygen masks, bandages, and tongue depressors. These devices are typically subject to general controls—such as manufacturing standards and labeling requirements—but are often exempt from premarket notification requirements.

Class II devices represent moderate risk and include products such as infusion pumps, surgical drapes, and contact lenses. These devices are subject to both general and special controls and generally require premarket notification through the 510(k) pathway, in which the manufacturer must demonstrate that the device is substantially equivalent to an already legally marketed device.

Class III devices, by contrast, are high-risk products that typically sustain or support life, are implanted, or present a potential for significant harm. Examples include ventilators, pacemakers, and implanted prosthetics. These devices require the most rigorous level of review through premarket approval (PMA), a process that involves detailed evaluation of safety and effectiveness, often supported by clinical trial data.

The 510(k) pathway is the most commonly used mechanism for bringing devices to market. Under this process, manufacturers are required to demonstrate that a new device is "substantially equivalent"to a predicate device—one that is already legally marketed. Substantial equivalence may be established by showing that the new device has the same intended use and technological characteristics as the predicate, or that any differences do not raise new questions of safety or effectiveness.[11]

This pathway offers clear advantages. It facilitates relatively rapid market entry, reduces development costs, and allows incremental innovation to proceed efficiently. For many devices—particularly those involving minor modifications or improvements—this approach is both practical and appropriate. However, the reliance on predicate devices also introduces potential limitations. Over time, chains of equivalence may develop in which new devices are approved based on predecessors that themselves were never subjected to rigorous contemporary evaluation. This phenomenon, while not inherently problematic, can create vulnerabilities when applied to more complex or higher-risk technologies.

In contrast, the premarket approval (PMA) process is designed to provide a more stringent evaluation for high-risk devices. PMA submissions typically include detailed information on device design, intended use, nonclinical testing, clinical trial data, and manufacturing processes. This pathway is more resource-intensive and time-consuming but offers a higher level of assurance regarding safety and effectiveness.

A third mechanism, the Investigational Device Exemption (IDE), allows for the use of investigational devices in clinical studies to collect safety and effectiveness data prior to formal approval. IDE studies require both Institutional Review Board (IRB) and FDA approval and are often used when a device introduces novel technological characteristics that raise new questions regarding risk. These studies are particularly important in fields characterized by rapid innovation, where clinical experience must be systematically gathered before broader adoption.

The practical application of these pathways can be illustrated by collaborative research efforts such as the U.S. Aortic Research Consortium, in which multiple academic centers pool data from individual IDE trials to generate more robust conclusions regarding complex endovascular therapies. Such models highlight both the strengths of distributed innovation and the necessity of coordinated data analysis in evaluating new technologies.

While these regulatory frameworks are designed to balance innovation with patient safety, they are not without criticism. The relative efficiency of the 510(k) pathway, in particular, has been both praised for enabling rapid technological advancement and questioned for its reliance on historical predicates. Similarly, the resource demands of the PMA process may limit the speed at which high-risk innovations reach clinical practice.

These tensions underscore a broader theme: regulatory systems must navigate competing priorities—facilitating innovation, ensuring safety, and managing the influence of industry. The effectiveness of these systems cannot be fully assessed at the point of market entry alone. Rather, it depends critically on what happens after devices are introduced into clinical use.

Post-Market Surveillance, Reporting, and Regulatory Actions

Regulatory approval marks the transition of a medical device from controlled evaluation to widespread clinical use, but it does not represent the endpoint of oversight. Indeed, many of the most consequential insights into device safety and performance emerge only after deployment in real-world settings. For this reason, post-market surveillance constitutes a critical component of the regulatory framework, particularly for devices that are complex, widely used, or associated with significant risk.

Post-market surveillance is designed to monitor the real-time performance of medical devices following their introduction into clinical practice. This process is especially important for Class II and Class III devices, where failures may lead to serious adverse health consequences. Surveillance requirements apply to devices that are implanted for extended periods (typically greater than one year), those that sustain life outside of controlled settings, and those used in vulnerable populations, such as pediatric patients.

A key feature of this system is that surveillance planning begins prior to market approval. Manufacturers are required to develop a post-market surveillance plan as part of their premarket submission, outlining how data will be collected, analyzed, and acted upon once the device is in use. Data sources may include user surveys, follow-up studies, and clinical registries, which provide longitudinal insights into device performance across diverse patient populations.

The responsibilities of surveillance are shared between manufacturers and clinicians. Physicians, as end-users, play a pivotal role in identifying complications, reporting adverse events, and contributing to registries. Manufacturers, in turn, are obligated to analyze incoming data and implement corrective actions when necessary. These actions may include modifying device labeling or instructions for use, issuing safety communications, providing additional training to users, or conducting further clinical studies to clarify risks.

Central to this system is the mandatory reporting of adverse events. Manufacturers are required to report any device-related complications or malfunctions that could result in serious injury or death to the U.S. Food and Drug Administration (FDA). In certain cases, healthcare providers may also submit reports directly. This reporting mechanism serves as an early warning system, enabling regulators to detect patterns that may not have been apparent during premarket evaluation.

When safety concerns are identified, the FDA has several mechanisms at its disposal to intervene. These include recalls, removals, and corrections, each representing a different level of regulatory response. A recall involves the removal of a marketed product that is deemed to be in violation of regulatory standards or to pose a significant risk to patients. A removal refers to the physical withdrawal of a device from its point of use for repair, modification, or other action, without necessarily implying a regulatory violation. A correction, by contrast, involves modification or relabeling of a device without its removal from clinical use.

These distinctions are not merely semantic; they reflect gradations in both risk and regulatory response. However, they also highlight a broader challenge: the effectiveness of post-market surveillance depends on timely detection, accurate reporting, and decisive action. Delays or deficiencies in any of these components can allow problematic devices to remain in use longer than is appropriate.

The regulatory landscape has also been shaped by legislative efforts to streamline approval processes and expand access to new technologies. The FDA Modernization Act of 1997 sought to accelerate the review of drugs and devices, facilitate patient access to experimental therapies, and focus post-market surveillance on higher-risk products. Among its provisions was the allowance for third-party review of certain Class I and Class II devices, reflecting an effort to reduce regulatory burden and expedite innovation.

While such measures have contributed to the rapid advancement of medical technology, they have also raised concerns regarding the balance between efficiency and safety. By shifting some aspects of oversight and prioritizing speed, these reforms may increase reliance on post-market surveillance as a compensatory mechanism. In effect, the system becomes more dependent on the ability to detect and respond to problems after devices have already entered widespread use.

This dynamic introduces an inherent risk: the possibility that significant device-related complications may only become apparent after large numbers of patients have been exposed. The implications of this risk are not theoretical; they are illustrated by several high-profile device failures, most notably the metal-on-metal hip implant crisis.

Case Study: The Metal-on-Metal Hip Implant Crisis

The theoretical vulnerabilities inherent in the device approval and surveillance system are most clearly understood when examined through specific clinical failures. Among the most consequential of these is the metal-on-metal hip replacement (MoMHR) crisis, which illustrates how regulatory pathways, industry incentives, and post-market surveillance can intersect with significant consequences for patient safety.

Metal-on-metal hip replacements were designed with a chrome–cobalt femoral head articulating against a chrome–cobalt acetabular socket. The rationale for this design included improved durability, reduced wear compared to earlier materials, and suitability for younger, more active patients. However, the pathway by which these devices entered the market is central to understanding the subsequent failure.[12]

Rather than undergoing the more rigorous premarket approval (PMA) process typically required for high-risk implanted devices, many metal-on-metal hip systems were approved through the 510(k) pathway, based on claims of substantial equivalence to predicate devices that had been marketed prior to the modern regulatory era. In some cases, these predicate devices had themselves been withdrawn from the market decades earlier. This reliance on historical equivalence allowed newer designs to bypass more stringent evaluation, expediting their introduction into clinical practice.

The scale of adoption was substantial. Between approximately 2003 and 2013, millions of metal-on-metal hip implants were placed worldwide. Initial enthusiasm for these devices was driven by theoretical advantages and early clinical acceptance. However, as post-market data began to accumulate, significant complications emerged.

By 2010, failure rates for these implants were reported to be 10 to 20 times higher than those observed with earlier metal-on-polyethylene designs from the 1970s. The underlying mechanisms of failure were multifactorial but centered on the generation of metallic debris at the articulating surfaces. This debris induced local inflammatory reactions, leading to soft tissue destruction, osteolysis, and, in severe cases, necrosis of surrounding structures.

A particularly important phenomenon identified in this context was mechanically assisted crevice corrosion (MACC), in which micromotion at modular junctions—such as the interface between femoral head and neck components—led to accelerated corrosion and release of metal ions. These processes were not fully anticipated during premarket evaluation and became evident only through widespread clinical use.

The clinical and economic consequences were profound. Large numbers of patients required revision surgery, often with greater technical complexity and higher morbidity than primary arthroplasty. Approximately one million patients in the United States were affected, with projected costs approaching $50 billion. Legal and financial repercussions were similarly significant, with litigation costs estimated at $45 billion, including major settlements by manufacturers.

Beyond these immediate impacts, the crisis exposed systemic vulnerabilities. First, it highlighted limitations of the 510(k) pathway when applied to complex, high-risk implanted devices. The concept of substantial equivalence, while efficient for incremental innovation, proved insufficient to capture the risks associated with fundamentally different biomechanical environments and long-term material interactions.

Second, the episode underscored the importance—and limitations—of post-market surveillance. While registries and reporting systems eventually identified the problem, this occurred only after widespread device implantation. In this case, national joint registries, particularly those outside the United States, played a critical role in detecting elevated failure rates and prompting regulatory action.

Third, the crisis illustrated the influence of industry dynamics. Rapid adoption of new technologies, driven in part by marketing, surgeon enthusiasm, and perceived competitive advantage, contributed to the scale of exposure before sufficient long-term data were available.

The metal-on-metal hip implant failure is therefore not simply an isolated historical event. It serves as a case study in the complex interplay between innovation, regulation, and industry influence. It demonstrates that even well-intentioned systems, designed to balance efficiency and safety, may produce unintended consequences when applied without sufficient scrutiny or when underlying assumptions—such as the validity of predicate equivalence—are not critically examined.

The Path Forward: Ethical, Institutional, and Policy-Level Responses

The preceding analysis underscores a central conclusion: the relationship between surgery and industry is both indispensable and inherently tension-laden. Attempts to eliminate this relationship would likely impede innovation and compromise the advancement of patient care. Conversely, an approach that relies solely on disclosure and assumes that transparency alone is sufficient risks minimizing the structural nature of influence. The question, therefore, is not whether this relationship should exist, but how it should be responsibly governed.

This challenge may be framed as a spectrum between two untenable extremes: complete disengagement from industry and uncritical acceptance of existing relationships. The path forward lies between these poles and requires coordinated efforts at multiple levels—individual, educational, institutional, and policy.

At the individual level, the responsibility begins with self-reflection and the establishment of clear personal boundaries. Surgeons must determine what types of industry relationships they are willing to accept and define thresholds for financial involvement that are consistent with their professional values. This includes consideration of consulting roles, research funding, equity participation, and speaking engagements. Equally important is the concept of recusal—the recognition that certain circumstances may warrant withdrawal from decision-making processes to preserve objectivity. This is not an admission of bias but a proactive measure to mitigate its potential.

At the training program level, the influence of attending surgeons on residents and fellows is particularly significant. Trainees develop their professional norms, in part, by observing how faculty navigate relationships with industry. Transparent and ethically grounded behavior by attending surgeons can therefore serve as a model for future practice. Conversely, unexamined or poorly managed relationships risk perpetuating patterns that may be difficult to reconcile with evolving standards of accountability. The issue of industry representative presence in the operating room further illustrates this dynamic. While such presence may be necessary for the safe introduction of new technologies, it must be carefully managed to avoid undue influence on clinical decision-making.

At the institutional level, more formal structures are required. Hospitals and health systems should establish independent review processes for evaluating new devices and technologies, separate from financial or strategic interests that may influence purchasing decisions. The creation of dedicated conflict-of-interest committees can provide a mechanism for assessing disclosed relationships and determining appropriate mitigation strategies. Importantly, institutions themselves may need to adopt thresholds at which they recuse their own decision-making authority, particularly when large capital investments—such as those associated with robotic platforms—create incentives that could shape clinical practice patterns.

Transparency in purchasing decisions and robust post-market surveillance systems are also essential components of institutional responsibility. By systematically collecting and analyzing outcomes data, institutions can identify potential safety concerns early and contribute to broader efforts to evaluate device performance. Such systems complement national and international registries, reinforcing a culture of continuous assessment.

At the policy level, the regulatory framework governing medical devices warrants ongoing refinement. The 510(k) pathway, while effective for facilitating incremental innovation, may require greater stringency in defining and applying the concept of substantial equivalence. Clarifying the criteria by which predicate devices are selected and limiting the extension of equivalence across multiple generations of devices could reduce the risk of unintended gaps in evaluation.

In addition, there is a growing recognition of the need for independent statistical analysis in industry-sponsored clinical trials. The perception—and in some cases the reality—of bias in such trials can undermine confidence in their findings. Ensuring that data analysis is conducted or verified by independent entities may enhance credibility and support more balanced interpretation of results.

Professional societies, including organizations such as American College of Surgeons and Society of American Gastrointestinal and Endoscopic Surgeons, also have a role to play. By developing and disseminating guidelines for managing industry relationships, these societies can provide a framework for ethical practice that is responsive to the realities of modern surgery. Such guidance can help standardize expectations across institutions and support surgeons in navigating complex professional environments.

Ultimately, the effectiveness of these measures depends not only on their formal implementation but also on the broader culture of the profession. The surgeon–industry relationship is shaped by shared norms, expectations, and values. Efforts to improve this relationship must therefore extend beyond compliance with regulations to encompass a commitment to ethical clarity and professional responsibility.

Conclusion

The relationship between surgery and industry is not a peripheral concern but a defining feature of modern surgical practice. It has enabled transformative advances, from the introduction of anesthesia and antisepsis to the development of minimally invasive and robotic techniques. At the same time, it has introduced complexities that challenge traditional notions of professional independence and clinical judgment.

As this analysis has shown, the central issue is not the existence of industry involvement, but the conditions under which it operates. Innovation and influence are not separate phenomena; they arise from the same underlying structures. The task, therefore, is to design systems that preserve the former while constraining the latter.

This requires a multifaceted approach: individual accountability, educational transparency, institutional oversight, and regulatory refinement. It also requires a willingness to critically examine established practices and to adapt in response to emerging evidence. The lessons of past failures, such as the metal-on-metal hip implant crisis, underscore the importance of vigilance and the need for continuous evaluation.

A quotation from Atul Gawande captures the ethos of this endeavor:

> "*Better is possible. It does not take genius. It takes diligence. It takes moral clarity. It takes ingenuity. And above all, it takes a willingness to try.*"

This perspective is both pragmatic and aspirational. It acknowledges the complexity of the surgeon–industry relationship while affirming the capacity of the profession to navigate it responsibly. In doing so, it reinforces a fundamental principle: that the ultimate measure of any system—whether technological, economic, or regulatory—is its ability to serve the interests of patients.

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